

INFORMATION LETTER

NATIONAL CANNERS ASSOCIATION

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For Members
Only

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November 26, 1960

FDA Prohibits Further Use of FD&C Red No. 1

On the basis of the results of recent animal feeding tests, the FDA has terminated the provisional listing of the color additive FD&C Red No. 1 (Ponceau 3R), and has cancelled all certificates issued for this color as of the date of publication of the order in the *Federal Register*.

The order was scheduled for publication in the *Federal Register* of November 26.

The effect of the FDA order is to prohibit the use of FD&C Red No. 1 in the manufacture of foods, drugs and cosmetics after the date of publi-

cation. Foods containing FD&C Red No. 1 which were packed or manufactured before that date are not affected by the order, but use of the color additive after that date will render the product adulterated under the Federal Food, Drug, and Cosmetic Act. If it can be shown that Red No. 1 was added to products after the date of publication of the order, such products will be subject to seizure and condemnation, and the packers will be liable for criminal penalties.

The FDA had previously listed FD&C Red No. 1, along with a number

The FDA is preparing to issue a general regulation under the Color Additives Amendment. story on page 305

of other food color additives in use as of July 12, 1960, as being deemed provisionally listed under the Color Additives Amendment of 1960 (see Supplement to the INFORMATION LETTER of Oct. 15). The effect of this provisional listing was to permit the continued use of these colors during a 2½-year period, unless and until data became available on which to establish a tolerance or to terminate the provisional listing.

Under the procedural provisions of the Color Additives Amendment, any person adversely affected by an order terminating the provisional listing of a color additive may file a petition objecting to the order, setting forth (or referring to) data which show that continued use of the color is consistent with the protection of the public health.

Following are pertinent portions of the FDA press release, issued November 22, and the text of the FDA order terminating the listing for FD&C Red No. 1:

John L. Harvey, Deputy Commissioner of Food and Drugs, today signed an order to eliminate the use of FD&C Red No. 1, a water soluble coal tar color that is widely used in a variety of foods as well as drugs and cosmetics. It is not used in lipsticks.

Mr. Harvey said the action was taken because preliminary experiments have shown that the color produces liver damage in test animals and no safe use level has been established.

He said that the test results did not provide a basis for concluding that the color could cause cancer. These tests, however, will be continued.

FDA is immediately discontinuing certification of any further batches of this color and is cancelling outstanding certificates for all previously certified lots. According to the order, "the Commissioner of Food and Drugs, having concluded that ingestion of this color additive over a long period of time would be unsafe, and in order to protect the public health, hereby ter-

George Romney, President of American Motors Corporation, To Be Principal Speaker at N.C.A. Convention

George Romney, president of American Motors Corporation, has accepted the invitation of President Milan D. Smith to be principal speaker at the N.C.A. Annual Meeting, opening the 1961 Canners Convention, January 23, in Chicago. He is expected to review the general economic situation and business outlook.

Mr. Romney has been president of American Motors since 1954, soon after formation of that firm. He had joined the Nash-Kelvinator Corporation in 1948. With the merger of Nash-Kelvinator and the Hudson Motor Car Company in 1954, American Motors Corporation was formed and Mr. Romney became executive vice president and a member of the board of directors. He was elected president in October of 1954.

Born in Chihuahua, Mexico, of American parentage, he came to the United States as a small boy. He attended University of Utah and George Washington University.

After serving in 1929 as a tariff specialist for U. S. Senator David I. Walsh, Mr. Romney joined the Aluminum Company of America and represented that company and the Aluminum Wares Association in Washington, D. C. In 1939 he became Detroit manager of the Automobile Manufacturers Association, the industry's national association, and later was general manager. He was president of that association from 1956 to 1958.

Mr. Romney has participated vigorously in community affairs, serving as chairman of the Detroit Citizens Advisory Committee on School Needs in 1957-58, and currently he is chairman of Citizens for Michigan, a statewide nonpartisan citizen group.

Canned Foods Problems Clinic

In preparation for the Canned Foods Problems Clinic which is to be held at the 1961 Convention, the N.C.A. Research Laboratories have invited members to indicate the technical questions they would most like to have answered.

The question-and-answer session will deal with plant maintenance and sanitation, and will present a panel of experts from the canning industry, the N.C.A., and other industries. The clinic is being designed primarily for operating personnel.

In a questionnaire mailed to members, the Laboratories have listed 50 questions on plant maintenance and sanitation, and have asked members to list the 10 they would most like to have on the agenda for discussion.

minates the provisional listing of FD&C Red No. 1 for use in foods, drugs, and cosmetics."

At the same time the Commissioner found "that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him, taking into account that the additive is not an acute toxic substance and that it is only used in small amounts in foods, drugs, and cosmetics."

FDA said that the lowest amounts of Red No. 1 which have been shown to produce liver damage in test animals were many times greater than the amounts of this color that would be consumed in the human diet.

The FDA action is being taken under the new color additive law, which places on manufacturers the burden of proving that colors are safe before they can be allowed in foods, drugs, and cosmetics. Heretofore there have been no limits on the amount of Red No. 1 that could be used in foods, although in practice the actual amounts have been small, even where Red No. 1 was the sole coloring agent used.

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

PART 8—COLOR ADDITIVES

FD&C RED NO. 1

Pursuant to the authority vested in the Secretary of Health, Education, and Welfare by Title II of the Color Additives Amendments of 1960 (Title II, Public Law 86-618; 74 Stat. 404 et seq.; 21 U.S.C., note under 376) and delegated to the Commissioner of Food and Drugs (25 F.R. 8625), the transitional color-additive regulations published in the *Federal Register* of October 12, 1960 (25 F.R. 9759) as amended October 19, 1960 (25 F.R. 9946) and November 5, 1960 (25 F.R. 10600) are further amended as set forth below:

1. Section 8.502 *Termination of provisional listings of color additives* is amended by adding thereto the following new paragraph (e):

(e) *FD&C Red No. 1.* Results of recent feeding tests of this color additive have demonstrated it to be toxic upon ingestion:

(1) Groups of 50 rats are being fed diets containing FD&C Red No. 1 at levels of 5 percent, 2 percent, 1 percent, 0.5 percent, and 0 percent. At this stage of the tests, which have now been in progress for from 15 months to 18 months, 116 animals from the 250 being fed FD&C Red No. 1 at various levels and 27 of the 100 controls have died. Of these, 11 being fed at the 5 percent level, 16 being fed at the 2 percent level, 11 being fed at the 1 percent level, and 2 being fed at the 0.5 percent level, have shown liver damage. None of the controls

that have died have shown liver damage.

(2) Groups of 100 mice are being fed diets containing 2 percent, 1 percent, 0.5 percent, and 0.1 percent FD&C Red No. 1, with 400 mice as controls. All mice on dosage levels of 2 percent and 1 percent died before the seventieth week. Gross liver damage has been observed in all groups fed at the 0.5 percent diet and above.

(3) Groups of 4 dogs are being fed diets containing 2 percent, 1 percent, 0.25 percent, and 0 percent FD&C Red No. 1. Three of the dogs on the 2 percent dosage level died before 32 weeks; the other is living. Three of the dogs on the 1 percent dosage level died or were sacrificed within 13 months. All deceased or sacrificed dogs have shown liver damage grossly and/or microscopically. Deceased dogs on the 1 percent and 2 percent dosage level showed poor physical condition.

The Commissioner of Food and Drugs, having concluded that ingestion of this color additive over a long period of time would be unsafe, and in order to protect the public health, hereby terminates the provisional listing of FD&C Red No. 1 (sec. 9.60 of this chapter) for use in foods, drugs, and cosmetics.

2. Section 8.510 *Cancellation of certificates* is amended to read as follows: Sec. 8.510 Cancellation of certificates.

(a) Certificates issued heretofore for colors being removed from the provisional list [Sec. 8.502(a)] are cancelled and of no effect after December 1, 1960, and use of such color additives in drugs or cosmetics after that date will result in adulteration.

(b) Certificates issued heretofore for the color additive designated FD&C Red No. 1 (Sec. 9.60 of this chapter) are cancelled as of the date of the publication of this Order, and use of this color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him, taking into account that the additive is not an acute toxic substance and that it is only used in small amounts in foods, drugs, and cosmetics.

Effective date. This order shall be effective upon publication in the *Federal Register*. Notice and public procedure are not necessary prerequisites to the promulgation of this order, because section 203(d)(2) of the Public Law 86-618 so provides.

(Title II, Public Law 86-618; 74 Stat. 404 et seq.; 21 U.S.C., note under 376)

Dated: November 22, 1960.

[SEAL]

JOHN L. HARVEY,
Deputy Commissioner
of Food and Drugs.

Revised Tariff Schedule Is Proposed to Congress

The U. S. Tariff Commission on November 15 submitted the final report of its study on tariff classification. The report constitutes a recommendation to Congress for revision of the laws under which imported articles are classified for tariff purposes.

The Commission's recommendations, if enacted into law, would establish a new system of classifying imported articles, superseding the present schedule, which was enacted in the Tariff Act of 1930.

The Commission's study was made at the direction of Congress. In the Customs Simplification Act of 1954 the Commission was directed to make a comprehensive study of the laws prescribing the tariff status of imported articles and to propose a revision of those laws.

Congress instructed the Commission to recommend a tariff schedule that would be logical in arrangement and terminology, adapted to the changes in import trade since 1930, and simple to apply.

Congress instructed the Commission generally not to recommend changes in rates of duty, and the Commission's report on tariff classification is not concerned, therefore, with tariff rates.

The proposed tariff classification provisions are organized into eight schedules, in contrast to the present 16. Canned food products are covered in "Schedule 1—Animal and Vegetable Products." Each of the schedules is divided into parts and subparts.

Copies of the Tariff Commission's proposed "Schedule 1—Animal and Vegetable Products" may be obtained from the Government Printing Office, Washington 25, D. C., for \$2.25 each.

Florida Vegetable Canners

W. Gordon Schmitt of Steinfeldt-Thompson, Dania, was elected president of the Florida Vegetable Canners Association at the group's second annual convention.

Samuel Sugarman, Sugar Rose Canning Co., Plant City, was elected first vice president; and R. L. Golden, Roberts Brothers, Inc., Winter Haven, second vice president. J. S. Peters of Orlando continues as secretary-treasurer.

List of Food Products on Which the U. S. May Reduce Tariffs

Announcement was made November 22 of a supplementary list of products on which the United States may consider offering tariff concessions in the tariff negotiations about to begin in Geneva.

This second "offer list" includes canned and frozen blueberries, sauerkraut, corned beef hash, canned sardines, canned anchovies, and canned smoked oysters. The list supplements one announced in May (see INFORMATION LETTER of June 4, pages 190-191).

In the trade agreement negotiations the United States may agree to reduce the rate of duty on any of the listed products, in exchange for "reciprocal" concessions from other countries on other products of similar value in trade.

The items in the supplementary list are described in official language in the announcement by the Interdepartmental Committee on Trade Agreements. That list includes the following food products:

Tariff Par.

- 718(a) Fish, prepared or preserved in any manner, when packed in oil or in oil and other substances:
- Sardines (except smoked sardines), neither skinned nor boned, valued over 30 cents per pound, including weight of the immediate container; and sardines, skinned or boned, and anchovies, valued over 9 cents per pound, including weight of the immediate container.
- 721(e) Oysters, smoked, packed in air-tight containers.
- 735 Berries, edible: Blueberries in their natural condition or in brine, or dried, desiccated, or evaporated, or otherwise prepared or preserved, or frozen, and not specially provided for; and other berries (except barberries) dried, desiccated, or evaporated.
- 769 Chickpeas or garbanzos, dried (not including split).
- 775 Bean stick, miso, bean cake, and similar products, not specially provided for; sauerkraut.
- 778 Hash, not specially provided for: Corned beef hash.

The Committee for Reciprocity Information will receive public views and comments favoring or opposing reductions in the U. S. tariffs on these products. Written statements should be submitted by December 27. The closing date for applications to be heard at the public hearings is December 27. Public hearings open January 5.

The Tariff Commission will follow the same schedule in connection with its "peril point" investigation on the extent to which U. S. concessions on the listed products may be made without causing or threatening serious injury to a domestic industry producing like or directly competitive products.

FDA Plans General Color Additives Regulation

Proposed regulations recently released by the FDA would, if finally adopted, resolve many of the questions that the N.C.A. and others have raised with regard to the scope and applicability of the Color Additives Amendment of 1960. These regulations, not yet formally proposed by the FDA, were made available at a November 17 open meeting held by the FDA to discuss with industry representatives problems raised by the Color Additives Amendment.

Representatives from the Association staff and counsel's office were among the more than 100 persons from industry and allied organizations present at the meeting. Much of the discussion involved the testing procedures that will have to be undertaken by color manufacturers in order to clear color additives for listing prior to the January, 1963, deadline, but FDA officials also commented on certain aspects of the proposed regulations that would clear up some of the uncertainties created by the extremely broad scope of the Amendment.

At the Congressional committee hearings on the Color Additives Bill, the N.C.A. had strongly objected to the broad definition of color additives proposed by the FDA, on the ground that it might cover virtually all foods and food ingredients—including natural substances—capable of imparting color. Congress chose, however, to accept the FDA proposal and refused to restrict expressly the scope of the definition (see INFORMATION LETTERS of Feb. 3, page 73; June 4, page 188; and July 2, page 205).

In an attempt to restrict by regulation the scope of the Color Additives Amendment, the Association filed a petition with the FDA in July of 1960 proposing the adoption of a regulation to the effect that ingredients used in standardized canned foods in compliance with definitions and standards of identity under the Federal Act are not color additives unless the ingredient is designated as a coloring substance in the standard (see INFORMATION LETTER of July 23, page 221). It was expected that other petitions would be filed by the Association with regard to ingredients in nonstandardized foods that might be capable of imparting color to food but which are not in fact used for coloring purposes.

In its proposed regulations, the FDA has apparently accepted the position of the N.C.A. that the Color Additives Amendment should be re-

stricted in its coverage to substances deliberately used for coloring purposes. The FDA regulations as drafted define in some detail the term "color additive," and contain the following sentences:

"Food ingredients, such as cherries, green or red peppers, chocolate, and orange juice, which contribute their own natural color when mixed with other foods, are not regarded as 'color additives.' But where a food substance, such as beet juice, is deliberately used as a color, as in pink lemonade, it is a 'color additive.' Food ingredients as authorized by a definition and standard of identity, prescribed by regulations pursuant to Section 401 of the Act, are 'color additives,' where the ingredients are specifically designated in the Definitions and Standards of Identity as permitted for use for coloring purposes."

If this definition of color additive is adopted as proposed, it should be unnecessary for canners to petition for a great number of exemptions under the Amendment, since it is made specifically clear that the term "color additive" will not cover food ingredients which contribute their own natural color when mixed with other foods. In addition, the N.C.A. position, as stated in its petition with regard to standardized foods, has been adopted in effect by the statement in the last sentence quoted above.

Although the proposed FDA regulations in many respects meet the major objections of the Association to the Color Additives Amendment, it is anticipated that the Association will nevertheless file some comments on the regulations after they have been formally proposed in the *Federal Register*. At that time the proposed regulations will be published in part in the INFORMATION LETTER, so that canners will be able to submit to the Association any comments or objections they might deem appropriate.

R. N. Ball

R. N. Ball of the Pacific Olive Co., Visalia, Calif., died November 17.

Mr. Ball was one of the founders of that firm. A graduate of the University of California, where he studied under Professor L. V. Cruess, Mr. Ball was strongly research minded. He had been for many years chairman of the Olive Technical Advisory Committee of the California Olive Association and a member of N.C.A.'s Western Laboratory Advisory Committee.

N.C.A. Officers and Staff Take Part in State Meetings

N.C.A. President Milan D. Smith was a principal speaker at the fall meeting of the Michigan Canners and Freezers Association, and Secretary Carlos Campbell and others of the N.C.A. staff presented industry reviews at the annual convention of the Pennsylvania Canners Association this week.

MR. SMITH IN MICHIGAN

Mr. Smith cited Michigan as an excellent example of how food technology in the United States surpasses that of Russia. An important reason for Russia's lag in food processing and distribution, he said, is the regimentation of agriculture under the Russian system. There, he pointed out, farmers are not free to bargain for their crops but either receive fixed wages for their farm work or deliver their crops according to government dictate at set prices.

Mr. Smith cited statistics which tend to establish Michigan's excellence in relation to Russia. For example, he said, the 66 canneries operating in Michigan are the equivalent of a third of Russia's entire canning industry. Also, Michigan with its land area of 58,216 square miles and its population of 8 million produces almost one-fifth as much canned food as does all of Russia with its territory covering a sixth of the earth's surface.

Highlights of Mr. Smith's address were reported in a press release issued by the N.C.A. Information Division to 261 newspapers and 51 radio-TV outlets in Michigan as well as to the local and national wire services and trade papers.

H. Thomas Austern, Chief Counsel of N.C.A., spoke and answered questions on the Robinson-Patman Act.

N.C.A. AT PENNSYLVANIA

Secretary Carlos Campbell introduced N.C.A. staff members at the Pennsylvania meeting for summaries of important developments in the industry.

Dr. Edwin A. Crosby, Assistant Director of the Raw Products Research Bureau, described how the N.C.A. has implemented the industry's "Protective Screen" program. He reported that industrywide effort seemingly has been successful in 1960 in avoiding a situation such as the cranberry episode, but emphasized that the pesticide chemical problem will continue to demand industrywide attention and action. He said that N.C.A. will continue to follow closely

Stocks of Canned Fruits on Nov. 1 and Season Shipments

(N.C.A. Division of Statistics)

	Case basis	Carry-over month	Supply		Canners' Stocks, Nov. 1		Season Shipments to Nov. 1	
			1959-60	1960-61	1959	1960	1959	1960
Apples.....	6/10	Sept.	2,763	2,508	2,001	1,580	762	928
Applesauce.....	actual	Sept.	12,871	13,776	9,336	10,333	3,535	3,443
RSP cherries.....	actual	July	4,326	2,555	2,359	1,330	1,907	1,225
Pineapples.....	actual	June	18,874	19,158	9,518	11,173	9,357	7,085
Pineapple juice*.....	actual	June	13,466	14,102	8,710	7,839	4,756	6,354

* Pineapple Growers Association of Hawaii.

the pesticide problems in the industry and will work with the FDA, agricultural experiment stations, the extension service, and USDA to protect all interests.

James W. Bell of the Washington Laboratory spoke on problems in administration of regulatory food laws. He noted that the food section of the recommended uniform state food, drug and cosmetic law has been adopted by only 31 states, and that lack of uniformity is more prevalent in regulations and enforcement than in state food laws themselves.

The food industry should promote raising the level of enforcement personnel from the standpoint of education and training, he said. Mr. Bell recommended adoption of a program for each plant to meet its sanitation needs and said that the attitude of management is of first importance in attaining the goals of the program.

Dr. H. L. Stier, Director of the N.C.A. Division of Statistics, presented a statistical review and outlook for canned foods. Referring to the general economic situation, he pointed out that per capita disposable income continued to rise throughout 1960 and, in real terms, reached an all-time high in the third quarter. Also, he reported that the strong demand for food is expected to con-

tinue in 1961. Total food supply during 1961 is expected to be slightly larger than during 1960, and the total 1960 production is expected to be the second highest of record. The carry-over stocks of canned fruits, vegetables and juices at the beginning of the 1960-61 season were the lowest in four years.

R. B. Heiney, Assistant Secretary, reported prospects for federal legislation under the new administration. He predicted that strong moves will be made to enact legislation dealing with wage-hour, marketing orders, raw product bargaining, cooperatives' marketing facilities, agricultural labor, and FDA factory inspection.

Wisconsin Canners Association

Donald E. Bonk of the Chilton Canning Co., Chilton, was elected president of the Wisconsin Canners Association at the annual convention.

Herbert Warner of Oconomowoc Canning Co., Oconomowoc, was elected vice president; C. A. Sias, Friday Canning Corp., New Richmond, treasurer; and Jerome Krier, Krier Preserving Co., Beloit, recording secretary. Marvin P. Verhulst, Madison, was continued in office as executive secretary.

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